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Research Article

Effect of Sucking Ice Bits Containing Chamomile (*Matric aria chamomilla*) Extract on the Chemotherapy-Induced Nausea and Vomiting among Cancer Patients

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Abstract

Background: Nausea and vomiting are some of the major side effects of chemotherapy in cancer patients that even makes them refuse treatment in some cases. In some studies, it has been shown that ice is useful to decrease nausea and has no effect on vomiting. On the other hand, the chamomile (*Matric aria chamomilla*) is used as a non-pharmacological treatment to decrease vomiting in many countries.

Purpose: The purpose of the present study was to investigate the effect of ice bits containing chamomile extract on the severity of nausea and vomiting.

Methods: The present clinical trial has been conducted on 60 cancer patients. The samples were selected using a convenience sampling method and divided into two groups using a random allocation method. The subjects of the intervention group were undergone bits of ice containing chamomile extract in addition to the routine treatments of the unit. The tests were performed at an error level of 5% using version 22 of SPSS software.

Results: In the first to third days of treatment, there was no significant difference between the two groups in the terms of the nausea and vomiting severity but on the fourth day, the severity of nausea and vomiting was significantly decreased in the intervention group compared to the control group.

Conclusion: Ice bits-containing chamomile extract may be a safe and simple adjunct together with anti-nausea and anti-emetic (or anti-vomiting) drugs in patients undergoing chemotherapy.

Keywords: *Cancer; Vomiting; Nausea; Chemotherapy; Ice Bits Containing Chamomile Extract*

Introduction

According to the latest statistics published by the WHO in 2011, cancer is the second cause of mortality in the world after cardiovascular diseases [1]. Chemotherapy, which is one of the therapeutic methods for cancer [2], can completely cure some types of cancer and relieve some others [3]. Chemotherapy-induced nausea and vomiting (CINV) is one of the most severe [4] and the worst side effects of chemotherapy. It is therefore of major concern to cancer patients [5-8] (the statement contradicts previous statements). The CINV can include nausea and acute, delayed and predictable vomiting [9]. Nausea and vomiting often occur in the acute phase [10,11], which usually begins

a few minutes after the injection and lasts 2 to 6 hours after the end of chemotherapy [12]. A cancer patient may refuse to continue treatment if the symptoms of nausea are not controlled [13-15]. Although anti-nausea and anti-vomiting drugs have significantly expanded in recent years, they can only decrease vomiting and their effect on nausea is often negligible [16]. On the other hand, the widespread use of industrial anti-vomiting drugs is associated with adverse effects such as hypotension, headache and extra-pyramidal side effects (EPSE) [17]. Considering the limited advantages and effects of conventional anti-nausea drugs, alternative and complementary therapies as well as the tendency to herbal remedies can be one of the essential and low-risk measures [17-19]. Ice therapy is a complementary treatment. Ice therapy is based on the theory that the coldness makes the mucus less expose to toxic agents by creating vasoconstriction and as a result, ice cold causes vasoconstriction in the peripheral parts of the digestive system (esophagus and stomach) and decrease the penetration of chemotherapeutic agents into these areas, which leads to a decrease in the irritation of digestive system stimulation and the severity of nausea and vomiting. According to the statistics of WHO, about 80% of the world's population currently utilize herbal remedies for treatment [20]. Chamomile is a herb which has the properties of anti-nausea and anti-vomiting, gastric soothing and strengthening and relaxing nerves in stressful situations [21]. It is derived from the daisy-like flowers of the Asteraceae plant family and has a prominent place in ancient medical and pharmaceutical texts. Chamomile is widely used in the world and in the Iranian pharmaceutical market as an anti-inflammatory, antispasmodic, anti-bloating, mouthwash and antibacterial drug as well as for treatment of gastric ulcer, removal of drying and cracking skin [22]. It is also used as an effective medicine to prevent vomiting [23,24]. Proper dosage of this drug has no side effect but due to side effects of any medication, it should be noted that allergic reactions, difficulty swallowing, noise violence and menstrual changes are rare side effects of this drug [25].

The effect of chamomile extract on the severity of chemotherapy-induced nausea and vomiting (CINV) has been investigated in several studies, but different results have been reported. However, it has been shown in a study that the patients are more likely to use ice to control CINV. Considering the effect of ice cold on decreasing the severity of nausea and vomiting in cancer patients and given the fact that no study has been conducted on the combination of these two effects, the purpose of present study was to investigate the effect of sucking ice containing chamomile (*Matric aria chamomilla*) extract on chemotherapy-induced nausea and vomiting (CINV) in cancer patients referred to Imam Khomeini Hospital.

Materials and Methods

The statistical population of present clinical trial included cancer patients referred to the oncology unit of Imam Khomeini Medical Center during the period of August 2019 to January 2020 (for 5 Months). Amongst them, 60 individuals were selected using convenience sampling method and divided into two groups using random allocation method. Sample size was of 54 was calculated (2 groups of 27 individuals) using G * Power statistical software based on the repeated measure ANOVA at significance level of 5% ($\alpha = 0.05$), with test power of 90% ($\beta = 0.1$), the mean effect size ($d = 0.25$) and 4 repetitions. Hence the sample size was determined equal to 30 patients for each group considering 10% of the additional sample in each group due to possible loss of samples.

Socio-demographic data (age, gender, education level) were collected through a personal information form and visual analog scale (VAS) for patient companion or the author as well as the frequency of vomiting cases based on number of occurrences. This tool was a 10-centimeter-long visual analog scale (VAS) for determining the severity of cases of nausea, where the participants were to mark a point on the line between 0 (no nausea), 1 - 3 (mild nausea), 4 - 6 (moderate nausea), 7 - 9 (severe nausea), and 10 (intolerable nausea) each time they felt nauseous.

The inclusion criteria of present study were the written consent to participate in research, cancer diagnosis, presence of gag reflex (pharyngeal reflex) with swallowing ability, literacy and eyesight. The exclusion criteria included restriction of fluid intake, patients on nil per oral (NPO) and patients with consciousness disorders.

Since the experiment was time-consuming, and there were a large number of samples (30 samples in the control group and 30 in the experimental group), the researchers examined the two groups on different days for more accurate examination and reduction of errors. Thus, the patients participating in the research were randomly divided into the control and experimental groups, with those undergoing chemotherapy on odd days of Iranian weekdays (Sunday, Tuesday and Thursday) considered as the control group and those undergoing chemotherapy on even days of Iranian weekdays (Saturday, Monday and Wednesday) regarded as the experimental group. It should be noted that the samples participating in the research were selected with a totally random method.

After obtaining written consent from patients, demographic information form was completed and the test was performed in both groups from half an hour before starting chemotherapy to 6 hours after receiving chemotherapy at the same sessions of chemotherapy for 4 days (due to the acute period up to 6 hours after receiving chemotherapy drugs). At the beginning of trial, nausea was measured through VAS. The number of vomiting episodes was also recorded in both groups. Participants in the control group received and the severity of nausea and the vomiting frequency of them were measured half an hour before chemotherapy, during chemotherapy and at the end of chemotherapy. Participants in intervention group received ice bits containing chamomile in addition to the routine treatment of chemotherapy unit so that they received 13 little ice bits with the size of one cubic centimeter and made up 1g of chamomile extract and 12 ml of distilled water. In this way, the patients received a bit of ice every half hour during the time intervals of half an hour before chemotherapy, during chemotherapy and up to 6 hours after chemotherapy and the severity of nausea and the vomiting frequency of them were measured during these time intervals. Also, it should be noted that the reason for choosing 1 gram of chamomile per day is that the dosage has been mentioned as the minimum appropriate dosage in most of the studies [26].

At the end of chemotherapy, the frequency of nausea, mean severity of nausea and vomiting frequency were recorded for patients in both groups. The analyses were performed at both descriptive and inferential levels after recording. At the descriptive level, mean and standard deviation indicators and statistical diagrams were used. According to the research design, the ANOVA with repeated measure of 2×2 was used for inferential level. The Bonferroni post hoc test was used to perform paired comparisons. The underlying assumptions of model including the normality of error distribution, homogeneity of variance error and data sphericity assumption were evaluated and validated using Shapiro-Wilk test, Levine test and Mauchly's Test, respectively. Mann-Whitney and Friedman tests were used to establish parametric tests whenever the parametric tests if conditions were not met. The tests were performed using version 22 of SPSS Software at the error level of 5%.

Findings

In present study, 4 individuals were excluded due to poor general condition and cancellation of chemotherapy session, 6 individuals due to lack of follow-up and failure to complete and deliver the questionnaires, and 2 due to death (12 individuals in total). To solve this challenge, 12 other patients were included replaced with the excluded individuals by extending the sampling time to maintain the sample size of 60 individuals.

In present study, 60 patients were divided into two groups of control and intervention and undergone chemotherapy. In both groups, 13 participants (43.3%) were females and 17 (56.7%) of them were males. The results of Chi-square test (Goodness_of_fit) showed no significant difference between the two groups in terms of gender distribution (P = 1.00). The mean age of the patients in the control group was 48.00 ± 10.11 years old and the mean age of the patients in the intervention group was 50.20±11.09 years old. The results of independent t-test showed no significant difference between the two groups in the term of patients, mean age (p = 0.425). In terms of education level, 16.7% of control group's patients were illiterate, 30.0% of them had diploma and 53.3% of them had university degrees. In the intervention group, 33.3% of patients were illiterate 33.3% of them had diploma and 33.3% of them had university degrees. The results of Chi-square test showed no significant difference between the two groups in the term of educational level (p = 0.212). The mean frequency of chemotherapy in the control group and the intervention group was 4.63 ± 2.09 and 5.38 ± 2.03, respectively. The result of Mann-Whitney test showed no significant difference between the two groups in this term (p = 0.159).

Figure 1, on that basis, the number of patients with severe nausea gradually decreased in the intervention group from the first to the fourth day, and the number of patients with mild nausea increased. So that 14 individuals (46.7%) on the first day, 5 individuals (16.7%) on the second day and 1 individual (3.3%) on the third day had severe nausea and on the fourth day, none of the patients in this group had nausea. Also, 12 individuals (40.0%) of this group had mild nausea on the first and second days, 16 individuals (53.0%) on the third day and 17 individuals (56.7%) on the fourth day had mild nausea. In contrast, the number of patients with severe nausea was 6 (20.0%) on the first day, 5 (16.7%) on the second day, 6 (20.0%) on the third day and 5 (16.7%) on the fourth day in the control group. Also, 12 individuals (40.0%) of this group had mild nausea on the first day, 13 individuals (43.3%) on the second day and14 individuals (46.7%) on the third and fourth days had mild nausea.

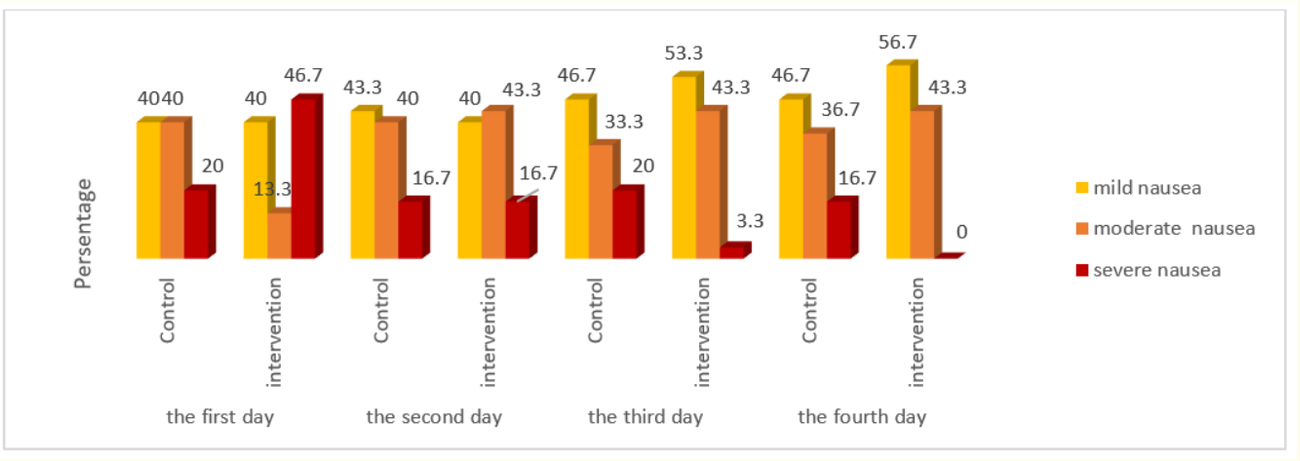

Figure 1: *The frequency distribution of patients in two groups based on the severity of nausea during the first to fourth days of treatment.*

Figure 2 represents the frequency distribution of patients based on their vomiting severity in the first to fourth days. Accordingly, the number of patients with severe vomiting was decreased in the intervention group during the first to fourth days and the number of patients without vomiting was increased so that 3 individuals (10.0%) on the first day and 1 individual (3.3%) on the second day had severe vomiting and none of the individuals had sever vomiting on the third and fourth days. Also, all of the individuals in the intervention group had vomiting on the first day, but 2 individuals (6.7%) on the second day and 8 individuals (26.7%) on the third day and11 individuals (36.7%) on the fourth day had no vomiting.

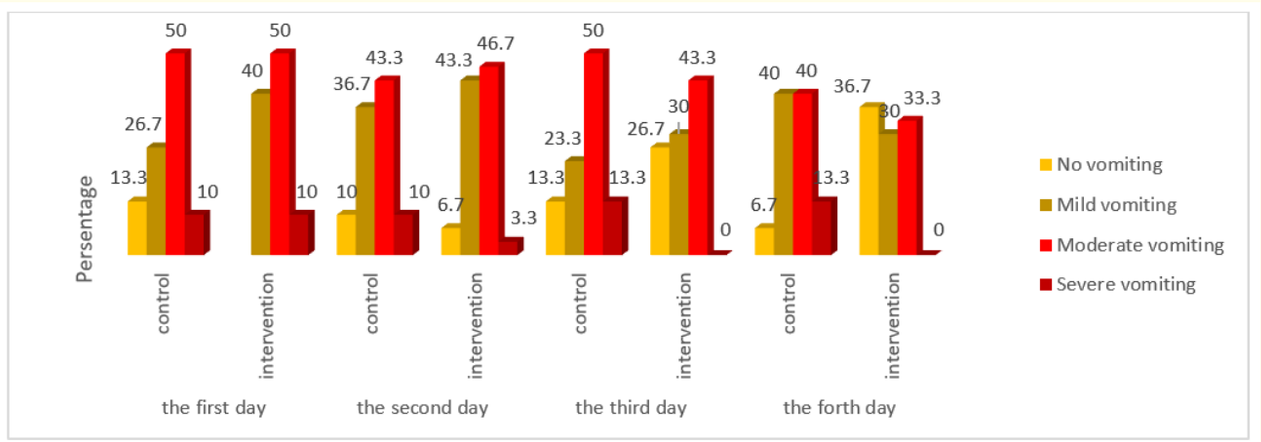

Figure 2: *The frequency distribution of patients in the two groups based on their severity of vomiting on the first to fourth days of treatment.*

In the control group, the number of patients with severe vomiting was 3 (0.10%) on the first and second days and 4 (13.3%) on the third and fourth days. Also, the number of individuals without vomiting were 4 (13.3%) on the first day, 3 (10.0%) on the second day, 4 (13.3%) on the third day and 2 (6.7%) on the fourth day (One decimal point is okay).

ANOVA with repeated measure was used to comprise the severity of nausea between patients of control and intervention group during the first and fourth days of treatment. The underlying assumptions of this model were investigated and the following results were obtained. The normality of the error distribution was evaluated using Kolmogorov–Smirnov test, which the assumption of error distribution normality was accepted on the first ($p = 0.0200$), second ($p = 0.083$), third ($p = 0.096$) and fourth ($p = 0.086$) days of treatment. Homogeneity of error variance between the two groups was evaluated using Levin test, which the assumption of error variance homogeneity was accepted on the first ($p = 0.074$) second ($p = 0.0389$), third ($p = 0.0810$) and fourth ($p = 0.069$) days of treatment. However, the sphericity assumption of data related to the severity of patients' nausea was rejected based on the results of Mauchly's Test ($p < 0.001$) and therefore, the Greenhouse-Geisser Test was used to adjust the degrees of freedom.

The nonparametric techniques were used to investigate the variables related to frequency of nausea and vomiting due to the lack of presuppositions for parametric tests. 0.344.

The mean frequency of nausea in both groups during the first to fourth days has been reported in table 1. According to the results of ANOVA with repeated measure, the assumption of means' equality was rejected on the first to fourth days ($^{2} = 0.344>0.001$, p (3, 2,123) = 362.30) but the effect of group-intervention interaction was not significant at the error level of 5% (F (1,58) = 0.706, $p = 0.404$, $^{2.} = 0.012$). Also, the effect of intervention group-measurement time was significant at the error level of 5% (F (3,123.2) = 26.80, $p>0.001$, $^{2.} = 0.316$). The results of post hoc test related to interaction effect indicated no significant difference between the nausea of patients in control group he first to fourth days ($p = 1.00$). In the intervention group, the mean frequency of nausea on the fourth day was significantly lower compared to the first, second ($p < 0.001$) and third days ($p = 0.008$), the mean frequency of nausea on the third day was significantly lower compared to the first and second days ($p < 0.001$) and its value on the second day was significantly lower compared to the first day ($p < 0.001$). Also, the comparisons of mean frequency of nausea between the patients of control and intervention group indicated no significant difference in the first ($p = 0.472$), second ($p = 0.772$) and third ($p = 0.122$) days. However, on the fourth day the mean severity of nausea in the intervention group was significantly lower compared to the control group ($p = 0.017$).

The mean frequency of nausea and vomiting of patients during the 4 days of chemotherapy has been reported in table 2. Mann-Whitney test was used to comprise the frequency of nausea between the two groups. According to the results, no significant difference was observed between the two groups in the term of patients' nausea frequency on the first day ($p = 0.073$); but the nausea frequency was significantly lower in the patients of intervention group on the second ($p = 0.038$), third ($p = 0.001$) and fourth ($p < 0.001$) days. Also, the results of Friedman test showed no significant difference between the nausea frequencies of patients in the control group during the first to fourth days ($p = 0.776$). In contrast, there was a significant difference between the nausea frequencies of patients in the intervention group on the four understudy days ($p < 0.001$). The post hoc test was performed with Bonferroni correction and the results showed no significant difference between the nausea frequencies of patients in this group on the first and second days ($p = 0.157$). However, in the second to fourth days, the frequency of patients' vomiting decreased significantly ($p < 0.001$).

Time of measurement-group	Control group		Intervention group		Results of repeated measures ANOVA (Effect size) p value		
	Mean	Standard deviation	Mean	Standard deviation	Time	Grossup	The interaction effect of time and group
The first day	4.87	2.18	5.32	2.60	0.001>	0.404	0.001>
The second day	4.75	2.14	4.58	2.24	0.344	0.012	0.316
The third day	4.81	2.25	3.92	2.10			
The fourth day	4.80	2.13	3.54	1.80			

Table 1: *The mean severity of nausea during the first to fourth days of treatment in the control and intervention groups and the result of repeated measures ANOVA test.*

The Mann-Whitney test was used to comprise the vomiting frequency between the two groups, which the results showed no significant difference between the patients of two groups in the term of vomiting frequency on the first (p = 0.062), second (p = 0.475) and third (p = 0.097) days; but on the fourth day (p = 0.010), the frequency of vomiting was significantly lower in the patients of intervention group. Also, the results of Friedman test showed no significant difference between the vomiting frequencies of patients in the control group during the first to fourth days (p = 0.448). In contrast, there was a significant difference between the nausea frequencies of patients in the intervention group on the four understudy days (p < 0.001). The post hoc test was performed with Bonferroni correction and the results showed a significant decrease in the vomiting frequency of patients during the first to fourth days (p < 0.001).

Variable	Group Time of measurement	Control group		Intervention group		P-value
		Mean	Standard deviation	Mean	Standard deviation	
The frequency of nausea	The first day	4.30	1.26	3.77	0.97	0.073
	The second day	4.27	1.31	3.57	1.14	0.038
	The third day	4.30	1.26	3.10	0.99	0.001
	The fourth day	4.33	1.18	2.67	1.21	0.001>
	P-value	0.776		0.001>		
The frequency of vomiting	The first day	3.46	1.56	3.27	1.64	0.626
	The second day	3.31	1.59	2.67	1.47	0.475
	The third day	3.18	1.72	2.77	1.27	0.097
	The fourth day	0.488	1.83	2.67	0.96	0.010
	P-value			0.001>		

Table 2: *The mean frequency of nausea and vomiting in patients during the first to fourth days of treatment in control and intervention groups.*

Discussion

In present study, the ice bits containing chamomile were used and the results showed a significant decrease in the severity of nausea, the frequency of nausea and the frequency of vomiting of patients in the intervention group during the first to fourth days of treatment. In contrast, no significant difference was observed in the patients of control group on 4 understudy days. Also, there was no significant difference between the two groups in the terms of nausea and vomiting frequency on the first to third days; but on the fourth day, the severity of nausea and vomiting was significantly lower in the intervention group compared to the control group. The frequency of nausea in the second to fourth days of treatment was also lower in the intervention group compared to the control group.

It should be noted that nausea and vomiting increase during chemotherapy [4] for this reason, patients receive anti-nausea and vomiting medication before chemotherapy to prevent these side effects. According to the values obtained in present study, it can be concluded that sucking ice bits containing chamomile extract has a positive effect on reducing nausea and vomiting.

In their study, Borhan., *et al*. (2017) concluded that chamomile extract can decrease the chemotherapy-induced nausea, but has no significant effect on the chemotherapy-induced vomiting [27]. On the other hand, Sanaati., *et al*. (2016) showed in their study that ginger and chamomile had no effect on the severity of nausea in patients with breast cancer undergoing chemotherapy and had only an effect on the frequency of their vomiting. The results are not consistent with the results of present study, which the difference can be justified by the type of research method or differences in the characteristics of the subjects [28].

In addition to the above studies, a study was conducted by Haddadi., *et al*. (2019) to investigate the effect of ice-cold sucking on nausea and vomiting during chemotherapy in breast cancer patients. The obtained results showed that ice containing simple water can decrease the nausea, but has no effect on the vomiting frequency [29]. The difference between the results of this study and the results of present study can be related to the type of research method, the duration of intervention and the effective factors of vomiting and vomiting.

Another study was conducted by Odarres M., *et al*. (2010) to comprise the effects of ginger and chamomile on decreasing the nausea and vomiting during pregnancy. The results showed that chamomile oral capsules were more effective in decreasing the pregnancy-induced nausea and vomiting compared to the ginger, which the finding is in consistent with the results of present study and emphasize the effect of chamomile on decreasing the nausea [30].

Based on the results of present study, it can be recommended to utilize ice containing chamomile extract as a part of the treatment for decreasing the chemotherapy-induced nausea and vomiting.

Conclusion

According to the results of present study, it is recommend utilizing ice containing chamomile extract alongside the drug therapy as a non-invasive, simple, inexpensive and without side effects to decrease the chemotherapy-induced nausea and vomiting among cancer patients. According to the results of present study, it can be stated that utilizing from ice bits containing chamomile extract at the recommended dosage has no adverse effects and can be used as a treatment in combination with other medical procedures to improve the condition and reduce side effects caused by chemotherapy.

Given the high importance of controlling the chemotherapy-induced nausea and vomiting and considering some inconsistent results in previous studies, the reason for the differences can be explained by the effective factors on severity of nausea and vomiting (diet, anxiety, gastrointestinal disease, etc). Therefore, it is recommendable to conduct a further study with the topic similar to the present study and taking into account the above mentioned factors. As a general conclusion from the findings of present study, it can be stated that the examined method of present study is an effective adjunctive therapy to decrease the level of chemotherapy-induced nausea and vomiting.

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